

REMARKS

I. Status of the Application

Claims 1-5 and 7-23 are currently pending in the application. Claims 18-22 have been withdrawn as non-elected species due to previous restriction requirements. Claims 9-17 stand objected to under 37 C.F.R. § 1.75(c) as being in improper form because of multiple dependencies. Claim 23 stands withdrawn as a constructively non-elected invention due to a restriction requirement. Claims 1, 2, 7, and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 97/31738 (hereinafter “WO ‘738) in view of U.S. Patent No. 4,569,821 to Duperray et al. (hereinafter “Duperray”) and U.S. Patent No. 2,686,958 to Eber et al. (hereinafter “Eber”). Claims 1 and 2 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over GB 1,004,352 (hereinafter GB ‘352) in view of Eber and Duperray. Claims 1-4 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,706,239 to Haack et al. (hereinafter “Haack”) in view of Eber and Duperray. Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Haack in view of Eber and Duperray, and further in view of WO ‘738. Claim 5 also stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Haack in view of Eber and Duperray, and further in view of WO 83/00282 (hereinafter “WO ‘282).

Applicants have amended the claims to more clearly define and distinctly characterize Applicants’ novel invention. Specifically, independent claims 1, 2, 3, and 23 have been amended to recite a method for preparing a porous metal implant or scaffold for tissue engineering. Support for these amendments can be found throughout the specification as filed, for example, in the abstract, at page 1, lines 1-7 and at page 11, lines 27-30. Claims 1 and 3 have been amended to recite the step of impregnating the polymeric foam with a slurry of metal particles. Support for this amendment can be found throughout the specification as filed, for example in the abstract, at page 3, lines 26-29, and at page 8, lines 20-25. Claims 3 and 23 have been amended to correct formal matters. Claims 7 and 8 have been amended to clarify that the metal particles are selected from the recited metals. Support for this amendment can be found throughout the specification as filed, for example at page 7, lines 12-16. Multiple dependent claims 7, 9-11, and 13-17 have been amended to depend from either claim 1 or claim 2. New

claims 24-34 having analogous subject matter to claims 7-17 have been added to retain the dependency of their subject matter on claim 3.

Applicants respectfully submit that the amendments herein present no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

II. Claim Objections

At page 2, third paragraph of the instant Office Action, claims 9-17 stand objected to under 37 C.F.R. § 1.75(c) as being in improper form because of multiple dependencies. Applicants have amended claims 7, 9-11, and 13-17 to remove multiple dependencies and to depend only from claim 1 (or claim 2 in the case of claims 15 and 17). In order to retain dependency on claim 3 of the subject matter of claims 7-17, new dependent claims 24-34 which are analogous to claims 7-17 have been added. Applicants respectfully submit that the subject claims are in proper form as a result of the present amendments. Accordingly, Applicants respectfully request withdrawal of the claim objections and examination of claims 9-17 and 24-34 on the merits.

III. Elections/Restrictions

At page 3, first paragraph of the instant Office Action, new claim 23 has been withdrawn from consideration as being directed to a non-elected invention. The Examiner is of the opinion that claim 23 is directed to an invention that is independent or distinct from the invention originally claimed. Applicants respectfully traverse the restriction requirement.

MPEP § 806.05(j) requires three components to reach a finding of distinctness between related process inventions: (A) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (B) the inventions as claimed are not obvious variants; and (C) the inventions as claimed are either not capable of use together, or can have a materially different design, mode of operation, function, or effect.

The Examiner has drawn a distinction between method claims 1-22 (invention I, class 419, subclass 2) and method claim 23 (invention II, class 419, subclass 26) as being directed to

mutually exclusive species in an intermediate-final product relationship. Applicants respectfully disagree. Claim 23 is very similar to claim 3, which the Examiner has grouped with invention I. Both claims 23 and 3 are directed to a method for providing a porous metal coating to a metal substrate. Thus, the two claims do not have a materially different function or effect. The methods of claims 23 and 3 recite analogous steps, such as adhering the source of the porous metal coating onto the metal substrate, drying the adhered composite, pyrolyzing in the presence of metal hydride particles that have been placed in a different location of the pyrolysis environment, and sintering in the presence of the metal hydride particles. Thus, claim 23 and claim 3 do overlap in scope. Also, the methods of the two claims do not have a materially different mode of operation. Therefore, claim 23 is not drawn to an invention that is distinct from Invention I, as exemplified by claim 3.

The Examiner has acknowledged that claim 23 and claim 3 are so similar as to belong to the same class of invention (class 419), and only differ by subclass. Since the Examiner has already searched and examined claim 3, and claims 23 and 3 are very similar for at least the reasons given above, Applicants respectfully submit that it would not be overly burdensome to the Examiner to search and examine claim 23. Accordingly, Applicants respectfully request withdrawal of the restriction requirement and examination of claim 23 on the merits.

IV. Claims 1, 2, 7, and 8 Are Patentable over WO '738 in view of Duperray and Eber

At page 4, last paragraph of the instant Office Action, claims 1, 2, 7, and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO '738 in view of Duperray and Eber. Applicants respectfully traverse the rejection.

Applicants submit that in order to establish a *prima facie* case of obviousness, there must be some motivation or suggestion to combine reference teachings with a reasonable expectation of success, and the combination of references must teach or suggest all the claim limitations.

Amended claims 1 and 2, from which the remaining subject claims depend, are directed to a method for preparing a porous metal implant or scaffold for tissue engineering. None of the cited references disclose a method for preparing a porous metal implant or scaffold for tissue engineering. WO '738 does not teach or suggest implants or tissue engineering scaffolds, but only refers generically to biomaterials as one of a long list of widely different applications ranging from gas and particulate filters to catalytic converters to cathodes (page 20, lines 6-12).

Duperray discloses a method of preparing a porous metal body which is particularly applicable to making electrodes for electrochemical cells (col. 1, lines 5-7), so Duperray does not teach or suggest an implant or tissue engineering scaffold. Eber discloses methods for forming a vacuum-tight metal-ceramic joint in electrical apparatus such as electronic tubes and the like (col. 1, lines 1-6), so Eber certainly does not teach or suggest an implant or tissue engineering scaffold. In fact, the combination of references would suggest a method for making electrical apparatus, since WO '738 discloses electro-chemical cathodes, Duperray discloses electrodes, and Eber discloses electronic tubes and the like. Thus the cited references fail teach, suggest, or provide motivation for a method for preparing a porous metal implant or scaffold for tissue engineering.

The Examiner may wish to argue that the preamble of claim 1 is of no significance to claim construction. However, if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claim preamble should be construed as if in the balance of the claim. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

Applicants submit that the preamble "a method for preparing a porous metal implant or scaffold for tissue engineering" is necessary to give life, meaning and vitality to independent claim 1 and its dependent claims, because it serves to further define the structure of the material. For example, a preamble reciting "an abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder, because it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an "abrasive article." Therefore, the preamble served to further define the structure of the article produced. *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Similarly, it is only by the preamble that it can be known that the subject matter defined by the present claims comprises a "method for preparing a porous metal implant or scaffold for tissue engineering." Every method for preparing a porous metal body is not a suitable method for preparing an implant or a scaffold for tissue engineering. The specification as filed discloses requirements for biocompatibility, corrosion resistance, pore size, porosity, and compressive

strength that should be met for use as implants (page 2, line 22 to page 3, line 2). For example, the method of Duperray is not suitable for preparing implants because it produces pore sizes of 7-100 microns (col. 3, lines 39-41), whereas the present application discloses that pore sizes for implants should be at least 400 μm , preferably at least 500 μm , and preferably not exceeding 800 μm (page 2, lines 26-28). Eber does not even mention methods for preparing porous metal bodies.

The Examiner is of the opinion that WO '738 discloses the methods recited in the subject claims with the exception of polymeric foam and the step of placing metal hydride particles in a different location in the pyrolysis or sintering environment. WO '738 makes no suggestion to modify its teachings to provide a polymeric foam, much less a polyurethane foam. Since WO '738 already teaches that the problem of undesirable reactivity of metals such as titanium with air, hydrogen, nitrogen, etc. at elevated temperatures is solved by pyrolyzing and sintering under vacuum (page 15, line 19 to page 16, line 7), the skilled artisan reading WO '738 would not be motivated to look for additional solutions to the problem of undesirable metal reactivity.

The Examiner relies upon Duperray to disclose polymeric foam, specifically polyurethane foam. But Duperray fails to remedy the deficiencies of WO '738. Duperray fails to teach the step of impregnating a polymeric foam with a slurry of metal particles, as recited in amended claim 1. Instead, Duperray incorporates metal powder (not a slurry of metal particles) into a water-based foam comprising surfactant and gelling agent (similar to gelled soap bubbles), and then adds only 2% to 9% by weight of a stabilizing agent, which polymerizes on contact with water, in order to set the water-based foam (col. 2, lines 12-16, 34-35, and 44-52). Thus Duperray does not teach a polymeric organic foam, but a water-based foam that is stabilized by a small percentage of polymer. In fact, Duperray teaches away from organic foams, e.g. polyurethane foam, teaching that the large proportion of organic matter in comparison with the metal component in metal-impregnated organic foams is a major source of drawbacks, such as shrinkage, reduction in porosity, and cracking, when heated to eliminate the organic matter (col. 1, lines 25-39). The method of Duperray is contrary to the method of WO '738, which impregnates an organic foam material (as opposed to Duperray's water-based foam) with a slurry of metal powder. Because of this teaching away, one of ordinary skill in the art would not be motivated to combine Duperray with WO'738 with any expectation of success.

The skilled artisan would also not be motivated to substitute the polymer-stabilized water-based foam of Duperray for the organic foam in the method of WO '738 with any expectation of success, because the method of Duperray is incompatible with the method of WO '738. WO'738 first provides an organic foam, and then coats the foam's surfaces with metal slurry (page 15, lines 5-7), whereas Duperray first provides a water-based foam, then suspends metal powder within its structure, and then sets (polymerizes) the foam around the metal powder (col. 2, lines 44-47). The steps of the two methods are in different orders: WO '738 provides (solid) organic foam and then coats the foam with metal powder, whereas Duperray stirs metal powder into a (non-solid) water foam and then sets or solidifies the foam. The two methods thus produce two different intermediates: WO '738 produces foam with metal powder coated on its surfaces, whereas Duperray produces foam with metal powder suspended/embedded within its structure). Since metal particles are already incorporated in Duperray's polymer-stabilized water-based foam, the skilled artisan would have no expectation that substituting Duperray's polymer-stabilized water-based foam in the method of WO '738, where the next step is further addition of metal particles by impregnating the foam with a slurry of metal particles, would successfully produce a porous metal implant or tissue engineering scaffold. If the Examiner is proposing to combine the method of WO'738 with Duperray's polymer-stabilized water-based foam minus metal particles, then Applicants respectfully submit that the Examiner is using improper hindsight reconstruction to pick and choose method steps from each reference to arrive at the claimed method.

The Examiner relies upon Eber to disclose placement of metal hydride particles in a different location of a vacuum chamber in an induction heater. But Eber fails to remedy the deficiencies of WO '738 and Duperray. Eber does not teach or suggest polymeric foam. Nor does Eber teach or suggest placing metal hydride particles in a pyrolysis or sintering environment. One of ordinary skill in the art of making metal implants and scaffolds for tissue engineering, looking to improve the manufacturing method, would not be motivated to look to Eber, which teaches in a nonanalogous art field. Eber is not related to medical apparatus or methods for making them. Eber is not even related to methods for producing porous metal articles. Instead, Eber teaches methods for forming a vacuum-tight metal-ceramic joint in electrical apparatus such as electronic tubes and the like (col. 1, lines 1-6). Since one skilled in the art of making metal implants and scaffolds for tissue engineering would not be expected to

look for references in the art of making electrical apparatus, the skilled artisan has no motivation to combine Eber with the above-mentioned references.

For at least the above reasons, WO '738, Duperray, and Eber do not provide motivation to combine their teachings with a reasonable expectation of success, nor do the references teach or suggest each and every claim limitation. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1, 2, 7, and 8.

V. Claims 1 and 2 Are Patentable over GB '352 in view of Eber and Duperray

At page 6, third paragraph of the instant Office Action, claims 1 and 2 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over GB '352 in view of Eber and Duperray. Applicants respectfully traverse the rejection.

As discussed above in section IV and incorporated herein by reference, amended claims 1 and 2 are directed to a method for preparing a porous metal implant or scaffold for tissue engineering. Neither the primary or secondary cited references disclose a method for preparing a porous metal implant or scaffold for tissue engineering, nor do the references suggest that their disclosed methods are suitable for preparing such implants or scaffolds. Specifically, GB '352 discloses metal foams suitable for use as seals in rotating equipment, filters, insulation, catalysts, and catalyst-carrying media (page 1, lines 15-17, page 8, lines 53-56). None of these mechanical and chemical applications suggests to the skilled artisan that GB '352 discloses a suitable method for preparing a porous metal implant or scaffold for tissue engineering. In fact, the combination of references would suggest a method for making electrochemical apparatus, since GB '352 discloses catalysts and catalyst-carrying media, Duperray discloses electrodes for electrochemical cells, and Eber discloses electronic tubes and the like. Thus the cited references fail teach, suggest, or provide motivation for a method for preparing a porous metal implant or scaffold for tissue engineering.

The Examiner is of the opinion that GB '352 discloses the methods recited in the subject claims with the exception of the step of placing metal hydride particles in a different location in the pyrolysis or sintering environment. Since GB '352 already teaches that the problem of undesirable oxidation of refractory metals, such as tantalum, by exposure to air at elevated temperatures is solved by sintering under vacuum or inert atmosphere, such as argon or helium

(page 2, lines 66-80), the skilled artisan reading GB '352 would not be motivated to look for additional solutions to the problem of undesirable metal reactivity.

The Examiner relies upon Eber to disclose placement of metal hydride particles in a different location of a vacuum chamber in an induction heater. The Examiner relies on Duperray for disclosing a method similar to GB'352 for forming a porous metal structure, and also for motivation to evacuate or trap the gas evolved from pyrolysis of polyurethane. But Eber and Duperray fail to remedy the deficiencies of GB '352. Duperray's method is not similar to that of GB '352 for analogous reasons as discussed in section IV above in the case of WO '738, so the skilled artisan would not be motivated to combine the methods of GB '352 and Duperray with any expectation of success. Duperray does not motivate the skilled artisan to look for additional methods of forming a vacuum beyond the standard vacuum pump. Duperray also would not lead the skilled artisan to look to Eber, which is nonanalogous art for reasons discussed above in section IV.

For at least the above reasons, GB'352, Eber, and Duperray do not provide motivation to combine their teachings with a reasonable expectation of success, nor do the references teach or suggest each and every claim limitation. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1 and 2.

VI. Claims 1-4 and 7 Are Patentable over Haack in view of Eber and Duperray

At page 7, second paragraph of the instant Office Action, claims 1-4 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Haack in view of Eber and Duperray. Applicants respectfully traverse the rejection.

As discussed above in section IV and incorporated herein by reference, amended claims 1 and 2, and also amended claim 3, are directed to a method for preparing a porous metal implant or scaffold for tissue engineering. Neither the primary or secondary cited references disclose a method for preparing a porous metal implant or scaffold for tissue engineering, nor do the references suggest that their disclosed methods are suitable for preparing such implants or scaffolds. Specifically, Haack discloses metal foams suitable for enhancing heat transfer processes such as steam generation, catalyzing chemical reactions or supporting catalysts, and acting as electrical elements such as a bipolar plate or a current collector for a fuel cell (col. 5, lines 38-59). None of these mechanical, chemical, and electrical applications suggests to the

skilled artisan that Haack discloses a suitable method for preparing a porous metal implant or scaffold for tissue engineering. In fact, the combination of references would suggest a method for making electrochemical apparatus, since Haack discloses fuel cell components, Duperray discloses electrodes for electrochemical cells, and Eber discloses electronic tubes and the like. Thus the cited references fail teach, suggest, or provide motivation for a method for preparing a porous metal implant or scaffold for tissue engineering.

The Examiner is of the opinion that Haack discloses the methods recited in the subject claims with the exception of the step of placing metal hydride particles in a different location in the pyrolysis or sintering environment. Haack does not recognize the problem of undesirable reactivity of metals with air and other gases at elevated temperatures. But since Haack teaches heating in a vacuum furnace under argon partial pressure (col. 5, lines 1-6, Example 1), which presumably removes reactive gases, the skilled artisan reading Haack would not be motivated to look for additional solutions to the problem of undesirable metal reactivity.

The Examiner relies upon Eber to disclose placement of metal hydride particles in a different location of a vacuum chamber in an induction heater. The Examiner relies on Duperray for disclosing a method similar to Haack's for forming a porous metal structure, and also for motivation to evacuate or trap the gas evolved from pyrolysis of polyurethane. But Eber and Duperray fail to remedy the deficiencies of Haack. Duperray's method is not similar to that of Haack for similar reasons as discussed in section IV above in the case of WO '738, so the skilled artisan would not be motivated to combine the methods of Haack and Duperray with any expectation of success. Duperray does not motivate the skilled artisan to look for additional methods of forming a vacuum beyond the standard vacuum pump. Duperray also would not lead the skilled artisan to look to Eber, which is nonanalogous art for reasons discussed above in section IV.

For at least the above reasons, Haack, Eber, and Duperray do not provide motivation to combine their teachings with a reasonable expectation of success, nor do the references teach or suggest each and every claim limitation. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1-4 and 7.

VII. Claim 5 Is Patentable over Haack in view of Eber and Duperray and further in view of WO '738

At page 9, first paragraph of the instant Office Action, claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Haack in view of Eber and Duperray and further in view of WO '738. Applicants respectfully traverse the rejection.

For reasons discussed in section VI above, the combination of Haack, Eber, and Duperray fails to render obvious claims 3 and 4, from which claim 5 depends. The Examiner admits that none of these references discloses titanium or titanium alloys, and relies upon WO '738 to disclose the use of titanium or titanium alloys in the method of claim 5. However, WO '738 fails to remedy the deficiencies of Haack, Eber, and Duperray. Since WO '738 already teaches that the problem of undesirable reactivity of metals such as titanium with air, hydrogen, nitrogen, etc. at elevated temperatures is solved by pyrolyzing and sintering under vacuum (page 15, line 19 to page 16, line 7), the skilled artisan reading WO '738 would not be motivated to look for additional solutions to the problem of undesirable metal reactivity. So WO '738 fails to provide motivation to combine the teachings of Eber with Haack or the other secondary references.

WO '738 does not teach or suggest implants or tissue engineering scaffolds, but only refers generically to biomaterials as one of a long list of widely different applications ranging from gas and particulate filters to catalytic converters to cathodes (page 20, lines 6-12). Since none of Haack, Eber, or Duperray is directed to biomaterials, much less to porous metal implants or scaffolds for tissue engineering, the skilled artisan would not be motivated to combine the cited references and then cherry-pick titanium, which is only disclosed by WO '738, to arrive at the method of claim 5, instead of using a metal common to all the cited the references such as nickel.

For at least the above reasons, Haack, Eber, Duperray, and WO '738 do not provide motivation to combine their teachings in the manner suggested by the Examiner, nor do the references teach or suggest each and every claim limitation. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 5.

VIII. Claim 5 Is Patentable over Haack in view of Eber and Duperray and further in view of WO '282

At page 9, fifth paragraph of the instant Office Action, claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Haack in view of Eber and Duperray and further in view of WO '282. Applicants respectfully traverse the rejection.

For reasons discussed in section VI above, the combination of Haack, Eber, and Duperray fails to render obvious claims 3 and 4, from which claim 5 depends. The Examiner admits that none of these references discloses titanium or titanium alloys, and relies upon WO '282 to disclose the use of titanium alloys to produce a prosthesis suitable for implant. However, WO '282 fails to remedy the deficiencies of Haack, Eber, and Duperray. Since WO '282 already teaches that the problem of undesirable oxidation of metallic alloys at elevated temperatures is solved by heating in a vacuum furnace or under a suitable inert atmosphere (page 6, lines 22-26), the skilled artisan reading WO '282 would not be motivated to look for additional solutions to the problem of undesirable metal reactivity. So WO '282 fails to provide motivation to combine the teachings of Eber with Haack or the other secondary references.

The skilled artisan would not be motivated to substitute titanium alloys from WO '282 in the method of Haack in view of Eber and Duperray, as suggested by the Examiner, because the method of WO '282 is substantially different from that of the primary reference, Haack. WO '282 applies a blend of primary metal particles and expendable (metal) particles to the surface of the substrate, compresses and heats so as to bond the particles each other and to the substrate, then chemically removes the expendable metal particles in a liquid bath to form pores (abstract, page 8, lines 11-16, page 7, lines 35-37). WO '282 does not impregnate a polymeric foam with metal powder slurry before heating to volatilize the polymeric foam and solidify the metal powder component, as does Haack, but instead obtains porosity by the completely different method of reacting and dissolving away expendable metal particles after all the metal particles are heat-bonded together. The skilled artisan would not have an expectation that titanium alloy particles from the method of WO '282 could be successfully substituted in the method of Haack.

For at least the above reasons, Haack, Eber, Duperray, and WO '282 do not provide motivation to combine their teachings in the manner suggested by the Examiner with any expectation of success. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 5.

IX. Interview Summary

Applicants would like to thank the Examiner for extending the courtesy of a telephone interview with Applicants' representative, Jane White, on December 15, 2006. The Examiner and Applicants' representative discussed proposed claim amendments and arguments against the present 35 U.S.C. § 103(a) rejections, and also arguments against the present restriction requirement.

X. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of this application. To the extent the Examiner believes it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

The Commissioner is authorized to apply any additional charges or any credits to our Deposit Account No. 19-0733.

Respectfully submitted,

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